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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION, and NOVARTIS AG Plaintiffs, v. SUN PHARMACEUTICALS INDUSTRIES, INC., SUN PHARMA GLOBAL FZE, CARACO PHARMACEUTICAL LABORATORIES, LTD, and SUN PHARMACEUTICAL INDUSTRIES LIMITED Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs Novartis Pharmaceuticals Corporation ("NPC"), Novartis Corporation, and Novartis AG (collectively, "Novartis"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This action relates to Abbreviated New Drug Application ("ANDA") Nos. 204051 and 204138 filed by Sun Pharma Global FZE with the U.S. Food and Drug Administration ("FDA") for approval to market generic versions of Novartis's Zometa® (ANDA No. 204051) and Reclast® (ANDA No. 204138) drug products, prior to expiration of U.S. Patent Nos. 7,932,241 ("the '241 patent").

PARTIES

2. Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Health Plaza, East Hanover, New Jersey.

3. Novartis Corporation is a corporation existing under the laws of the State of New York, with its principal place of business at 608 5th Avenue, New York, New York.

4. Novartis AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. Upon information and belief, Sun Pharmaceuticals Industries, Inc. ("Sun Pharma") is a corporation organized and existing under the laws of Michigan, having its principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey.

6. Upon information and belief, Sun Pharma is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for distribution in the U.S. market, including in this judicial district.

7. Upon information and belief, Sun Pharma Global FZE ("Sun Global") is a corporation organized and existing under the laws of the United Arab Emirates, having its principal place of business at Office #43, Block Y, SAIF-Zone (Sharjah Airport International Free Zone), P.O. Box. #122304, Sharjah, United Arab Emirates.

8. Upon information and belief, Sun Global is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for distribution in the U.S. market, including in this judicial district.

9. Upon information and belief, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") is an entity organized and existing under the laws of the State of Michigan with a principal place of business at 1150 Elijah McCoy Drive, Detroit, MI 48202.

10. Upon information and belief, Caraco is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for distribution in the U.S. market, including in this judicial district.

11. Upon information and belief, Sun Pharma, Caraco, and Sun Global are wholly-owned subsidiaries of Sun Pharmaceutical Industries, Ltd. ("Sun Industries") and are controlled and/or dominated by Sun Industries at the direction, under the control, and for the benefit of Sun Industries. Upon information and belief, Sun Industries established Sun Pharma and Caraco for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district. Upon information and belief, Sun Industries relies upon Sun Global at least in part to assist in obtaining regulatory approval for the development, manufacturing, and distributing of its generic drug products throughout the United States, including in this judicial district.

12. Upon information and belief, Sun Industries is a corporation organized and existing under the laws of India, having its principal place of business at 17-B Mahal Industrial Estate, Mahakali Caves Road, Andheri (E), Mumbai 400 093, India.

13. Upon information and belief, Sun Industries is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for distribution in the U.S. market, including in this judicial district, through various directly or indirectly owned operating subsidiaries, including Sun Pharma, Sun Global, and Caraco.

14. Upon information and belief, Sun Pharma, Sun Global, Caraco, and Sun Industries act in concert with one another and hold themselves out as an integrated unit for purposes of developing, manufacturing, distributing, marketing, and selling generic drug products throughout the United States, including in this judicial district.

15. Upon information and belief, Sun Pharma, Sun Global, Caraco, and Sun Industries acted collaboratively and in concert in the preparation and submission of ANDA Nos. 204051 and 204138.

16. Upon information and belief, the preparation and submission of ANDA Nos. 204051 and 204138 were done at the direction, under the control, and for the direct benefit of, and in concert with, Sun Industries.

17. Upon information and belief, following any FDA approval of ANDA Nos. 204051 and 204138, Sun Pharma, Sun Global, Caraco, and Sun Industries will act in concert with one another, and with other Sun Industries subsidiaries, to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA Nos. 204051 and 204138 throughout

the United States, and/or import such generic drug products into the United States, including in this judicial district.

18. Sun Pharma, Sun Global, Caraco, and Sun Industries are collectively referred to hereafter as "Sun."

JURISDICTION AND VENUE

19. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

20. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

21. This Court has personal jurisdiction over Sun Pharma because it has availed itself of the legal protections of the State of New Jersey by, among other things, maintaining its principal place of business in Cranbury, New Jersey.

22. This Court also has personal jurisdiction over Sun Pharma because, among other things, it has committed, or aided, abetted, contributed to, or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to NPC, a corporation with its principal place of business in New Jersey.

23. This Court also has personal jurisdiction over Sun Pharma because, among other things, as described above, it manufactures, distributes, markets, and sells generic drug products throughout the United States and within New Jersey. Furthermore, upon information and belief, Sun Pharma derives substantial revenue from such conduct in New Jersey. Accordingly, Sun Pharma has persistent, systematic and continuous contacts with New Jersey and has therefore purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in this district.

24. This Court has personal jurisdiction over Sun Global because, among other things, it has committed, or aided, abetted, contributed to, or participated in the

commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to NPC, a corporation with its principal place of business in New Jersey.

25. This Court also has personal jurisdiction over Sun Global because, among other things, as described above, it manufactures, distributes, markets, and sells generic drug products throughout the United States and within New Jersey. Furthermore, upon information and belief, Sun Global derives substantial revenue from such conduct in New Jersey. Accordingly, Sun Global has persistent, systematic and continuous contacts with New Jersey and therefore purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in this district.

26. This Court has personal jurisdiction over Caraco because, among other things, it has committed, or aided, abetted, contributed to, or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to NPC, a corporation with its principal place of business in New Jersey.

27. This Court also has personal jurisdiction over Caraco because, among other things, as described above, it manufactures, distributes, markets, and sells generic drug products throughout the United States and within New Jersey. Furthermore, upon information and belief, Caraco derives substantial revenue from such conduct in New Jersey. Accordingly, Caraco has persistent, systematic and continuous contacts with New Jersey and therefore purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in this district.

28. This Court has personal jurisdiction over Sun Industries because, among other things, it has committed, or aided, abetted, contributed to, or participated in the

commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to NPC, a corporation with its principal place of business in New Jersey.

29. This Court also has personal jurisdiction over Sun Industries because, among other things, as described above it manufactures, distributes, markets, and sells generic drug products throughout the United States and within New Jersey. Furthermore, upon information and belief, Sun Industries derives substantial revenue from such conduct in New Jersey. Accordingly, Sub Industries has persistent, systematic and continuous contacts with New Jersey and therefore purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in this district.

30. This Court also has personal jurisdiction over Sun Industries because it has availed itself of the legal protections of the State of New Jersey by, among other things, creating a subsidiary with its principal places of business in New Jersey (*i.e.*, Sun Pharma).

31. This Court also has personal jurisdiction over Sun because it has availed itself of the legal protections of the State of New Jersey by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

32. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Sun.

PATENT IN SUIT

33. On April 26, 2011, the U.S. Patent and Trademark Office duly and legally issued the '241 patent, entitled "Pharmaceutical Products Comprising Bisphosphonates." A true and correct copy of the '241 patent is attached hereto as **Exhibit 1**. Novartis is the owner of the '241 patent by assignment, with the right to sue for and obtain equitable relief and damages for infringement of the '241 patent.

34. NPC is the holder of NDA Nos. 21-223 and 21-386 by which the FDA granted approval for the marketing and sale of the equivalent of a 4 mg/ 100 mL dosage strength of zoledronic acid, which NPC markets in the United States under the trade name "Zometa®." Zometa® is covered by claims of the '241 patent. The FDA's official publication of approved drugs (the "Orange Book") includes Zometa® together with the '241 patent.

35. NPC is the holder of New Drug Application ("NDA") Nos. 21-817 and 22-080 by which the FDA granted approval for the marketing and sale of the equivalent of a 5 mg/ 100 mL dosage strength of zoledronic acid, which NPC markets in the United States under the trade name "Reclast®." Reclast® is covered by claims of the '241 patent. The FDA's official publication of approved drugs (the "Orange Book") includes Reclast® together with the '241 patent.

INFRINGEMENT BY SUN

36. By letter dated June 1, 2012, ("the First Notice Letter"), Sun notified Novartis that Sun had submitted ANDA No. 204051 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of a zoledronic acid solution containing the equivalent of 4 mg/ 100 mL of zoledronic acid as the active ingredient before the expiration of the '241 patent. Upon information and belief, Sun intends to engage in the commercial manufacture, use, and sale of its zoledronic acid solution containing the equivalent of 4 mg/ 100 mL of zoledronic acid as the active ingredient promptly upon receiving FDA approval to do so.

37. By filing ANDA No. 204051, Sun has necessarily represented to the FDA that its zoledronic acid solution containing the equivalent of 4 mg/ 100 mL of zoledronic acid has

the same active ingredient as Zometa®, has the same method of administration, dosage form, and strengths as Zometa®, and is bioequivalent to Zometa®.

38. In the First Notice Letter, Sun notified Novartis that its ANDA No. 204051 contained a "Paragraph IV certification" asserting that the '241 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Sun's zoledronic acid solution containing the equivalent of 4 mg/ 100 mL of zoledronic acid (generic Zometa®).

39. By letter dated July 5, 2012, ("the Second Notice Letter"), Sun notified Novartis that Sun had submitted ANDA No. 204138 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of a zoledronic acid solution containing the equivalent of 5 mg/ 100 mL of zoledronic acid as the active ingredient before the expiration of the '241 patent. Upon information and belief, Sun intends to engage in the commercial manufacture, use, and sale of its zoledronic acid solution containing the equivalent of 5 mg/ 100 mL of zoledronic acid as the active ingredient promptly upon receiving FDA approval to do so.

40. By filing ANDA No. 204138, Sun has necessarily represented to the FDA that its zoledronic acid solution containing the equivalent of 5 mg/ 100 mL of zoledronic acid has the same active ingredient as Reclast®, has the same method of administration, dosage form, and strengths as Reclast®, and is bioequivalent to Reclast®.

41. In the Second Notice Letter, Sun notified Novartis that its ANDA contained a "Paragraph IV certification" asserting that the '241 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Sun's zoledronic acid solution containing the equivalent of 5 mg/ 100 mL of zoledronic acid (generic Reclast®).

42. This Complaint is being filed before the expiration of the forty-five days from the date Novartis received the First and Second Notice Letters.

COUNT I (INFRINGEMENT OF THE '241 PATENT)

43. Each of the preceding paragraphs 1 to 42 is incorporated as if fully set forth herein.

44. Sun's submissions of ANDA Nos. 204051 and 204138 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of zoledronic acid solutions containing the equivalent of 4 mg/ 100 mL and 5 mg/ 100mL of zoledronic acid as the active ingredient prior to the expiration of the '241 patent constitutes infringement of one or more of the claims of the '241 patent under 35 U.S.C. § 271(e)(2)(A).

45. Upon FDA approval of Sun's ANDA Nos. 204051 and 204138, and unless enjoined by the Court, Sun will further infringe the '241 patent by making, using, offering to sell, and selling its zoledronic acid solutions containing the equivalent of 4 mg/ 100 mL and 5 mg/ 100 mL of zoledronic acid as the active ingredient in the United States and/or importing such solutions into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c).

46. Upon information and belief, Sun had actual and constructive knowledge of the '241 patent prior to filing ANDA Nos. 204051 and 204138 and was aware that filing of these ANDAs, with the aforementioned Paragraph IV certifications, constituted an act of infringement of the '241 patent.

47. If Sun's infringement of the '241 patent is not enjoined, Novartis will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

1. A judgment that one or more valid, enforceable claims of the ’241 patent are infringed by Sun’s submissions of ANDA Nos. 204051 and 204138, and that Sun’s making, using, offering to sell, or selling in the United States, or importing into the United States Sun’s zoledronic acid solutions containing the equivalent of 4 mg/ 100 mL and 5 mg/ 100 mL of zoledronic acid as the active ingredient will infringe the ‘241 patent.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA Nos. 204051 and 204138 shall be a date which is not earlier than the latest expiration date of the ‘241 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

3. An order permanently enjoining Sun, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or in concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Sun’s zoledronic acid solution containing the equivalent of 4 mg/ 100 mL of zoledronic acid as the active ingredient until after the latest expiration date of the ‘241 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

4. An order permanently enjoining Sun, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or in concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Sun’s zoledronic acid solution containing the equivalent of 5 mg/ 100 mL of zoledronic acid as the active ingredient until after the latest expiration date of the ‘241 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

5. Damages or other monetary relief to Novartis if Sun engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of

Sun's zoledronic acid solution containing the equivalent of 4 mg/ 100 mL of zoledronic acid as the active ingredient prior to the latest expiration date of the '241 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

6. Damages or other monetary relief to Novartis if Sun engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Sun's zoledronic acid solution containing the equivalent of 5 mg/ 100 mL of zoledronic acid as the active ingredient prior to the latest expiration date of the '241 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

7. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: July 13, 2012

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I certify that to the best of my knowledge, the matter in controversy is the subject of *Novartis Pharmaceuticals Corporation et al. v. Wockhardt USA LLC et al.*, Civil Action No. 2:12-cv-03967-SDW-MCA filed on June 27, 2012 in the District of New Jersey.

Dated: July 13, 2012

Respectfully Submitted,

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